



State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

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06-02 AMENDED

TO: California Physicians

FROM: Howard Backer, M.D., M.P.H., Chief
Immunization Branch

SUBJECT: Implications of a New California Law on Influenza Vaccine Orders for the
2006-2007 Influenza Season

Dear Colleague:

Recent California legislation, *The Mercury Free Act of 2004*, Chapter 837, Statutes of 2004 (AB 2943, Pavley), will limit the administration of mercury-containing vaccines to pregnant women and children younger than 3 years old. As a consequence of this legislation, effective July 1, 2006, it will be against California law (Health and Safety (H&S) Code Section 124172) to administer doses of inactivated influenza vaccine from a multi-dose vial to pregnant women or children younger than 3 years old because of the level of the mercury-containing preservative, thimerosal, contained in multi-dose vials. Effective July 1, 2006, only doses of influenza vaccine from single-dose syringes or vials with trace levels or no mercury may be given to these groups. This law does not apply to persons who are 3 years of age and older and who are not pregnant.

To order the appropriate formulation of influenza vaccine for the 2006-07 influenza season, health care providers need to consider this new law and to estimate the number of their vaccinated patients who will be pregnant or younger than 3 years. Pre-booking for certain influenza vaccine manufacturers and distributors is beginning this month. As in previous years, orders for federally-purchased influenza vaccine through the Vaccine For Children (VFC) program will occur separately from orders for privately-purchased vaccine. The information on the following pages is provided to assist you in complying with this new law when ordering influenza vaccine.

A) The following influenza vaccine meets the new law's mercury limit and is currently licensed for use in children younger than 3 years old:

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
Sanofi Pasteur Inc.	Fluzone® no preservative pediatric dose (children 6-35 months of age)	prefilled 0.25 mL unit dose syringes

B) The following influenza vaccines meet the new law's mercury limit and may be given to pregnant women:

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
Chiron Corporation	Fluvirin® preservative-free – <i>check with manufacturer or distributor regarding availability in 2006-2007 season</i>	prefilled 0.5 mL syringes
GlaxoSmithKline	Fluarix®	prefilled 0.5 mL unit dose syringes
Sanofi Pasteur Inc.	Fluzone® no preservative	0.5 mL unit dose vial
Sanofi Pasteur Inc.	Fluzone® no preservative	prefilled 0.5 mL unit dose syringes

C) The following influenza vaccines meet the new law's mercury limit but are not currently licensed for use in children under 3 years old:

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
GlaxoSmithKline	Fluarix®	prefilled 0.5 mL unit dose syringes
MedImmune Inc.	FluMist® <i>FluMist® is also <u>not</u> currently indicated for use in pregnant women</i>	prefilled 0.5 mL unit dose nasal sprayer

D) The following influenza vaccines do not meet the new law's mercury limit:

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
Chiron Corporation	Fluvirin®	5 mL multi-dose vial
Sanofi Pasteur Inc.	Fluzone®	5 mL multi-dose vial

Immunizations against diseases other than influenza

A few other vaccine preparations whose mercury content exceeds the limits of the new law are given infrequently to young children and pregnant women. These include certain formulations of the DT, Td, TT, and meningococcal polysaccharide vaccines for which acceptable alternatives are available. The California Department of Health Services Immunization Branch will issue additional guidance about the new law's implications before its July 1, 2006 effective date.

Additional Resources

The text of the new law, California Health and Safety (H&S) Code Section 124172 is available for review at

<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=124001-125000&file=124172>

For more information about mercury and vaccine safety, please visit:

<http://www.cdc.gov/nip/vacsafe/concerns/mercury/default.htm>

<http://www.immunize.org/safety/mercury.htm>

<http://www.fda.gov/cber/vaccine/mercury.htm>

http://www.cispimmunize.org/aap/aap_main.html?http&&www.cispimmunize.org/fam/thim.html

For additional questions about this topic, please contact either

- 1) Your local health department's immunization program, which is listed at <http://www.dhs.ca.gov/ps/dcdc/izgroup/provider.htm> under "Vaccine Programs - Local Health Department Listing", or
- 2) Nisha Gandhi at California Department of Health Services Immunization Branch, telephone (510) 620-3732.

cc: Immunization Branch Field Representatives
Local Health Department Immunization Coordinators
Local Health Department Health Officers